



UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT

Applicants: Robert D. Harty

Application: MODULAR NECK PROTECTION DEVICE

Serial No.: 10/687,162

Filing Date: October 16, 2003

Examiner: Tajash D. Patel

Art Unit: 3765

Conf. No.: 6814

Case No.: 0006/01146

CERTIFICATE OF MAILING

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Marilynn Oleck
Name of Representative

Marilynn Oleck
Signature of Representative

August 24, 2007
Date of Signature

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

20 North Wacker Drive
Chicago, IL 60606
312-621-1330

37 CFR 1.132 AFFIDAVIT OF MR. ROBERT HARTY

Dear Sir:

ROBERT HARTY, as sole inventor of the instant invention, hereby declares as follows.

1. I am president and a founder of Hazmat Medical, a privately owned company specializing in the design, development and sale of hazardous material supplies, ambulance supplies, medical equipment and support tools.
2. I have been involved with emergency medical service since 1970. In 1974, I obtained an EMT Certification. In 1977, I obtained a Paramedic Certification. I have been certified as a paramedic in Illinois, Ohio and

Nevada. Formerly, I worked as a fire/paramedic with the Chicago Fire Department.

3. I have provided lectures and educational materials to fire department, EMS agencies, and hospitals nation-wide on the art of handling emergency medical patients. I have taught at University Medical Centers and Level I Trauma Centers throughout the U.S.
4. I own three patents, all medical devices. In addition, I have multiple patents pending on other medical products (i.e. surgical table, cervical collar, OB-GYN products, etc).
5. Working as a paramedic for 20+ years, I have treated numerous head and neck injuries that resulted in death and permanent paralysis. Many of these patients showed no obvious signs of trauma, but they had fractured their necks falling backwards off of their bicycle, or roller blades, etc.
6. Doing research after realizing the long-felt need for a product as I have designed I found a number of distressing statistics. For example, according to the National Head Injury Foundation and the Center for Disease Control (CDC), approximately 50,000 people die each year in the United States from Traumatic Brain Injury (TBI). Over one million (1,000,000) are seen in emergency department with TBI. A TBI event occurs every 21 seconds in the United States. The largest segment of these patients is those between the ages of 15-19 years of age, and the number one cause is falls.
7. I worked for a number of years to design and develop an upper neck protector which would be lightweight and provide protection during everyday activity.
8. The result of my work is the neck protection design disclosed in the presently pending patent application with serial number 10/687,162.
9. I consider myself to be a person of ordinary skill in the medical device design industry by reason of founding and operating Hazmat Medical over the past 14 years during which time I have become intimately familiar therewith.
10. I understand the Examiner to contend that my claimed invention is obvious in light of U.S. Patent Nos. U.S. Patent No. 3,657,739 to Holmes, Sr., U.S. Patent No. 5,005,374 to Spitler, and US Patent 5,557,807 to Hujar.

11. I do not believe that a person of ordinary skill in the art would consider either the Holmes or Spittler art, alone or together, to be relevant to the invention as now claimed. Specifically, if a neck protection piece is added in place of the rounded indentation of Holmes, the neck protection would impact the wearer's neck and put pressure on the wearer's neck rather than protecting the wearer. Furthermore, the strap configuration on the Holmes invention causes the entire guard piece to rest against the wearer's back at the rounded indentation. Therefore, if a neck guard was added to the indentation, it would essentially put the entire weight of the Holmes invention on the wearer's neck.

12. Further, the Holmes invention requires straps to be placed around the wearer's torso. Unlike the present invention, the Holmes invention is not free hanging. Consequently, the Holmes invention and other prior art devices cannot be worn by those undertaking sports or leisure activities. Due to their encumbering nature, participants in sports choose to go unprotected rather than burdening themselves with covers such as Holmes.

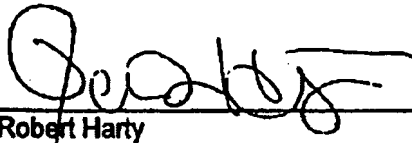
13. The suggested combination of the two inventions also defeats the purpose of the Spittler device. The embodiment disclosed in Spittler, which includes a neck device, is intended to function as a temperature control collar. Given that its sole purpose is cooling, the neck device must have minimal weight so as not to burden the wearer. Combining the thermal wrap with any features not designed for cooling of the body would defeat the purpose and benefits of the Spittler invention. Also, as Spittler explains, the neck is the only place where contact should be made since significant amounts of heat are exchanged through the wearer's neck.

14. The present invention is intended as a brace, and as such, it must make contact with the wearer's neck. Contact with the wearer's neck would impact air exchange and therefore defeat the cooling feature of Hujar. Furthermore, the cooling device in Hujar is shown placed on the outside of the cap so as to avoid contact with the person's neck as contact with a wet neck protector would result in an unpleasant sensation to the wearer.

15. The present invention is an injury prevention device, designed to reduce deaths, brain stem injuries and cervical spine injuries. It is not a cervical collar which is designed for use only after the injury has occurred for purposes of immobilization of the patient. Instead, the present device is designed to prevent injury.

16. The undersigned declares that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and may jeopardize the validity of any resulting patent.

June 11, 2007
Date



Robert Harty